What is the translation of HSCL-25 in Castilian; A consensus procedure by Delphi-round and Forward-Backward translation

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Par **Mlle FLAMANT Caroline**

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Présentée par Mr le Professeur Jean-Yves LE RESTE

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What is the translation of HSCL-25 in Castilian;

A consensus procedure by Delphi-round and Forward-Backward translation.

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Mlle FLAMANT Caroline, Interne en médecine générale.

Fait à BREST, le

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Serment d'Hippocrate

Au moment d'être admis à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admise dans l'intimité des personnes, je tairai les secrets qui me seront confiés.

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List of Abbreviations

DSM: Diagnostic and Statistical Manual of Mental Disorders

EGPRN: European General Practice Research Network

GP: General Practice

GPs: General Practitioners

FPDM: Family Practice Depression and Multimorbidity

HSCL-25: Hopkins Symptom Checklist in 25 items

NI: National Investigator

IIT: International Investigation Team

RAND/UCLA: Research ANd Development corporation and the University of California Los Angeles

HSCL-25 Forward-Backward translation to Castilian by Delphi Procedure. Third Phase of FPDM

Résumé

Introduction : Les médecins généralistes européens sont le premier recours des patients dépressifs. Les patients de plus de 50 ans multi-morbides sont plus à risque d'épisodes dépressifs. Les variations interindividuelles et interculturelles peuvent modifier l'expression des symptômes. En soins primaires, peu d'outils diagnostiques sont adaptés et utilisés.
L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) a pour objectif de sélectionner un outil diagnostique de la dépression en médecine générale. Des recherches européennes collaboratives entre médecins généralistes de différents pays et entre médecins généralistes et psychiatres pourront être réalisées.
Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25-items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie, versus DSM.

Objectif : L'objectif était de traduire la HSCL-25 en Castillan sans perte de sens mais cette traduction devait être compréhensible par les médecins et les patients, en prenant en compte les particularités culturelles et linguistiques du Castillan.

Méthode : Une procédure Delphi adaptée avec traduction Aller-Retour a été utilisée. Une traduction de l'Anglais au Castillan a été soumise par procédure Delphi à un panel d'experts en soins primaires. La traduction retour a été réalisée en aveugle de l'original.

Résultats : Le panel d'experts répondait aux critères d'inclusion. La traduction castillane a été validée après deux tours. La traduction retour en anglais a été produite.

Discussion : Le choix d'une méthode de traduction Aller-Retour par procédure Delphi adaptée et la qualité du panel d'experts garantissent une traduction castillane validée et fiable de la HSCL-25. La prochaine étape est une analyse culturelle de la traduction qui assurera la reproductibilité sémantique entre la version originale et la traduction.

Abstract

Introduction: General Practitioners (GPs) are the first port of call for depressive patients in developed countries. The multi-morbid patients over 50 years are more at risk. Inter-individual and intercultural variations may change the symptoms expression. Few diagnostic tools are adapted and used by GPs.
Family Practice Depression and Multimorbidity (FPDM) study by European General Practice Research Network (EGPRN) aims to select a depression diagnostic tool in primary care to undertake collaborative research involving GP's and Psychiatrists throughout Europe.
The two previous steps of FPDM found that the Hopkins Symptom Checklist in 25-items (HSCL-25) was the most appropriate tool according to effectiveness, reproducibility and ergonomics criteria versus DSM.

Objective: This study aimed to translate HSCL-25 in Castilian, keeping its meaning. This translation must be understandable by practitioners and patients, according to Castilian cultural and linguistic features.

***Method*:** A Delphi method adapted for a Forward-Backward translation was used. The Forward translation from English to Castilian was submitted by Delphi procedure to a panel of primary care experts. The Backward translation was performed blind.

Results: The inclusion criteria of panel were followed. The Castilian translation was accepted in one round. English back-translation was produced.

Discussion: Delphi method adapted for a Forward-Backward translation and the experts panel quality ensured a validated and reliable Castilian translation of the HSCL-25. The following step will consist in a cross-cultural check. Concordance between the original HSCL-25 and the Back-translation will be analysed.

Introduction

Depression is the second most common chronic disorder in general practice.(1) GPs are the first port of call in most European Countries. The multi-morbid patients over 50 years are more at risk of depression.(2-6)

Depression is a variable combination of symptoms shared with other mental disorders like contextual distress, anxiety and somatoform disorders. The patient himself experiences difficulties to express his suffering and shows his own illness expression.(7)

The difficulties to diagnose and assess the severity of depression lie in this inter-individual variability.(8-10) Clinicians can overestimate or underestimate the distress level of their patients.(11)(8) Those difficulties may lead to inappropriate care and cause public health problems.(4, 12-15) Diagnostic and Statistical Manual of Mental Disorders (DSM) is widely considered as the gold standard to diagnosing depression(16), but it's rarely used in General practice.(17-18) In addition, General Practitioners (GPs) seem to be uncomfortable with the definition of depression and available diagnostic tools.(19)(8) Incidence and prevalence rates of depression differ in General practice across Europe(27–31). This is related to complex contextual variations with differences in health care system, in concepts, objectives and practices as well as cultural variations in the expression of the disease.(20-24)

European GPs community needs a better knowledge of usable instruments to diagnose depression in adult patients.(21) There is also a need for a European consensus on a diagnostic tool for depression to undertake collaborative research in General practice throughout Europe.(25)

The Family Practice Depression and Multi-morbidity study (FPDM) started in 2011.The aim of FPDM study was to select a tool that could be consensually used by GPs to diagnose adult patient's depression and to make it applicable in the participating European countries. In order to be satisfying, it had to be efficient, reliable and easy to use by GPs throughout Europe. This study consisted of four steps.

The first step was a systematic review of literature (SRL), in order to select the candidate tools. The SRL investigated all diagnostic tools that were validated for depression versus DSM, in adult patients excluding pregnant and post-partum women. At the end of this step, seven tools were selected.(26)(2)

The second step was a consensus procedure aiming to select a single tool among the seven candidates. The method chosen to reach a consensus was RAND/UCLA (Research ANd Development corporation / University of California Los Angeles) procedure.(27) HSCL-25 was designated to be the most appropriate tool for depression diagnosis in adult patients in General practice in Europe, according to its criteria combined of effectiveness, reliability and ergonomics.(2)

The third step consisted in translating this tool in the language of each country taking part in the FPDM study, following the same formal consensus method (28), with the support of European General Practice Research Network (EGPRN). The HSCL-25 was used but there is no official and consensual translation available.

In many Spanish regions, the GP and his patient will either communicate in Spanish (Castilian), or in a regional language (as Catalan, Galician,…). Since emotional expression is intrinsically linked to the patient´s linguistic and cultural environment, it seems preferable to offer him a questionnaire written in his native language. This allows a broader, fairer, and more adequate use in daily practice, as

well as permitting to conduct stronger and more relevant research by taking into account Spain's linguistic diversity. (6)

The aim was to translate HSCL-25 in the three official languages of Spain: Castilian, Galician and Catalan.

This study aimed to translate HSCL-25 in Castilian.

Method

Definition

The HSCL-25 is a self-report questionnaire on the existence and severity of both anxiety and depression symptoms during the previous week, used to identify psychiatric illness in primary care.(It includes 25 items: 10 items about anxiety and 15 about depression.(29,30) The patient is considered as a “probable psychiatric case” if the mean rating on the HSCL-25 is ≥ 1,55. A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as “a case, in need of treatment”.(30) The HSCL-25 was used in family planning services, among refuges and among migrants.(31-33)

For the translation to retain the same meaning as the original, a Forward-Backward translation(34)(28) was conducted following a formal consensus method: Delphi round.(35) Formal consensus is the most appropriate method when there is a need to reach a solid consensus transparently on a little investigated subject.(36) Delphi procedure, reliable and efficient is used frequently in health care as a rigorous way to reach consensus in defined clinical areas.(37,38) It is a systematic interactive method which involves a panel of experts using iterative procedures. It can be done quickly to make a single convergent final recommendation. This process requires to follow four rules: anonymity of participants (ensures responses’ reliability and avoids contamination), iteration (allows participants to refine their views in the light of the progress of the group's work), control feedback (under the responsibility of national investigator (NI)), statistical aggregation of group’s responses to allow a quantitative and qualitative analysis of the data. (27,37,38)

Consents and anonymity

The NI asked the participants for their signed consent, anonymized the expert responses and delivered an identification number for later identification.(27) The name of each expert was not transmitted to others. Only NI’s consent was sent to the international investigator senior coordinator. As the study involved no patient, it did not require an ethics committee‘s decision.

Participants

International investigation team (IIT): The EGPRN French team was familiar with the Delphi methodology. It requested to the NI his consent and voluntary participation in the study and an absence of conflict of interest statement. It ensured that the whole process followed the protocol. It didn’t take part of the translation phases or in Delphi rounds. The Forward-Backward translation had to be validated by the daily board of the study, composed of members of the EGPRN, all active within the research process.

National Investigator (NI): The NI was in charge of recruiting translators and experts. He acted between each phase and between two Delphi rounds. He didn't act when a Delphi round was running.

Translators: The NI selected translators to make up two independent translation teams (one for Forward an one for Backward translation respectively). Translators had to be knowledgeable about health care terminology. The Forward translation team involved one member of the GP research group and one official translator. Castilian had to be their native language. The Backward translation team involved one (or two) GP(s) and one official Castilian/English translator.(39) The two teams should not have involved the same person.(40)(28)

Experts panel: Initially, 20 to 30 experts were recruited in order to keep at least 15 participants until the end of the last round. The selection criteria for every expert were: being native to Spain and having Castilian as their native language; being an English speaker; being in GP practice. Over half had to have teaching or research activities. In order to assess the representativeness of the panel by its diversity, the experts informed their gender, area of practice, years of practice and publications.

Forward Translation

The IIT sent the HSCL-25 original English version to the NI who sent it to the Forward translation team. This team translated HSCL-25 from English to Castilian aiming to retain the same meaning as the original.

Delphi rounds

At the beginning of the first round, NI sent by mail the original English version and the Forward translation in Castilian with all the rules of procedure. GPs experts received records individually. NI didn't use a mailing list in order to assure anonymity which increases the reliability of responses and avoids contamination (discussion between experts).(41)

Experts expressed their level of agreement on each proposal by using a Likert scale.(42,43) This Likert scale was an agree/disagree scale of 1 to 9, symmetric, odd, that measured the intensity of their feelings on each proposal, taking into account the maintenance of the meaning between the original and the translation proposal, the ergonomics and the ease of understanding. Experts rated the proposal from 1 (absolutely no agreement) to 9 (fully agreement) and had to comment when rating less than 7. Consensus was defined for an excerpt's translation when it was rated 7 or above by over 70% of the panel, (so it was accepted directly and didn't enter the following rounds; if not (proposal didn't reach consensus), the NI and the Forward official translator synthesized experts comments to propose a new translation proposal for this excerpt. Time between two rounds had to be less than four weeks. The following round began when the NI sent to the experts separately for each proposal that didn't reach consensus: the original English version, the unaccepted proposal with all the experts' comments on this proposal and the new proposal. Experts rated the new proposal in the same way as the first round. The following rounds rolled out in an identical manner. This process was repeated until all excerpts found a consensual translation. The number of rounds was not limited.

At the Delphi procedure end, there was a consensus on a final Castilian version of HSCL-25.

Backward translation

NI sent the final Castilian version of HSCL-25 to the Backward translation team who had to translate it into English. The translators should not have the knowledge of the original version (blind-back translation principle). Finally, he sent the English Back-translation to the IIT. (44)

Results

Forward

The NI submitted the questionnaire to one Official Translator and three GP researchers. A consensual forward translation of HSCL-25 was proposed. (Table 3.1) The native language of translators was Castilian and they were knowledgeable about health care terminology.

Panel

The NI obtained experts consents as well as the characteristics of each (Table 1).

Thirty-one GPs were recruited for the Delphi Process. They were all FPs in family practice and English speakers, according to the selection criteria.

The panel consisted of 20 (=64.51%) male and 11 (=35.49%) female. Experts worked in a city > 5000 (29/31=93.54%), in a small city (2/31=6.45%) and none worked in rural city <2000 (0/31).

Clinical experience was analysed by year of activities: *0-10 years* 7/31 (=22.58%); *11-20 years* 9/31 (=29.03%); *20-30 years* 13/31 (=41.94%); *30-40 years* 2/31 (=6.45%).

Among the 31 FPs experts, 27/31 (=87.10%) were academic researcher and 30/31 (=96.77%) had publications; none had teaching activity. Finally 31/31 (=100%) were academic researcher or had publications.

Delphi Procedure

A single Delphi rounds lasted two weeks.

The NI oversaw but didn’t take part of the rounds.

The procedure of Delphi rounds was applied: the NI sent the proposed translation with a « single recipient mail » to each expert; every original English excerpt was directly followed by its translation proposal and finally by a Likert scale of 1 to 9.

The entire proposals were validated with 7 or above (average of GP’s responses concerning each item).

Ten items of HSCL-25 were rated between 7 and 8 (Items 1 (7.806), 3 (7.968), 5 (7.935), 12 (7.742), 14 (7.71), 16 (7.903), 18 (7.839), 19 (7.968), observations (7.677), explanations (7.483). All other items were rated more than 8. (Table 2)

Discussed items of Forward translation and commentaries:

-The item 26 (Table 3.2) with lower average 7.483 and five experts rating less than 7: GP rating 1/9 made the proposition « …trastorno mental, AUNQUE debe ser evaluado de forma independiente mediante entrevista clínica YA QUE depende del diagnóstico y del género »; and commented it to allow better understand limitations of this (and any) test (« creo que así se entiende mejor la limitación de este test - como de cualquier otro - en la evaluación individualizada, en definitiva la que es determinante »)

Two GPs rated 2/9. One of the propositions on comments was « La puntuación del HSCL-25 (en un rango de 1,00 a 4,00) se calcula dividiendo la puntuación total (la suma de las puntuaciones de cada pregunta) entre el número de preguntas respondidas ». Same FP noted that « distress » can't be traduced by « ansiedad » in this sentence, commenting « ¿no estamos hablando de un instrumento para cribar la depression?, ¿quizá mejor 'malestar psicológico'? ». Other one made propositions: « entre el número de items respondidos » instead of « entre el número de respuestas »; « el nivel de sufrimiento » instead of « el malestar psicológico »; « caso psiquiatrico probable » instead of « probable caso psiquiatrico ».

Two GPs didn't agree with the traduction of « gender » by « genero" suggesting « sexo ».

-The item 27 (Table 3.2) with average 7.677, three experts rating less than 7, and six experts rating 7: Alternative translations were proposed: « síntomas ansioso y depresivos » or « síntomas de ansiedad y depression » or « presencia e intensidad de síntomas de ansiedad y depression ». In other sentence is proposed « eligen una de entre cuatro categorías para cada item ».

-Item 12 with average 7.742 and seven experts rating < 7: Their propositions were « Se siente culpable », « sentimiento de culpa », « se autoculpa ».

-Item 14 with average 7.710 and seven experts rating < 7: Alternative propositions were « ha perdido el interés sexual », « ha perdido el deseo sexual », « perdió el apetito sexual », « le apetecen las relaciones sexuales igual que antes? », « perdió interes por el sexo ».

-Item 1 with average 7.806 and five experts rating < 7: One expert explains that « tener miedo" is different from « asustarse » because the last one implies reaction. The propositions are « estar asustado sin motive », « se asustaba sin motive », « tiene miedo sin motive ».

-Item 18 with average 7.839 and seven experts rating < 7: They proposed « piensa en quitarse la vida », « piensa en sacarse la vida », « pensó en suicidarse », « ha pensado en acabar con su vida ».

-Item 16 with average 7.903 and four experts rating < 7: Those four experts proposed « sentimiento de desesperanza », « se siente desesperado », « se sentía desesperado ».

-Item 8 with average 7.935 and five experts rating < 7: Two experts suggested « tiene dolor de cabeza », and « tuvo dolor de cabeza ».

-Item 19 with average 7.968 and four experts rating < 7: Three experts proposed the same set expression « se siente como en callejon sin salida? ». Last expert proposed « ¿se siente que está como en un pozo y no puede salir? »

-Item 4 with average 7.968 and four experts rating < 7: The two propositions were « se siente nervioso", and « se siente nervioso por el mismo motivo que el anterior »

-Item "ranging 1 to 4" (Table 2 and Table 3.2) with average 8.032 and four experts rating < 7 had seven same comments about confusion risk to mistake "en absoluto" for "absolutely" while it is meaning "not at all". One expert proposed "'No, de ningún modo" witch signification is unambiguous.

-Item 11 with average 8.065 and five experts rating <7: They proposed "bajo de energía" or "falta de energía" to traduce "feeling low in energy".

Backward translation

NI sent the final Castilian version of HSCL-25 to four translators forming the backward translation team who translated it back to English. They were knowledgeable about health care terminology. One was a philologist and the three others were GPs. The blind-back translation principle was respected. English Back translation was finally sent to the IIT. (Table 3.1)

Differences relieved between ORIGINAL AND Back translation

Following excerpts had differences between the Original and the Back-translation.

Anxiety items collected few comments and there were few changes in Back translation. For example, in item 3 "faintness" was replaced by "weakness". In item 5 "heart racing" was changed for "palpitations".

Depressive items had many variations, in item 11 "feeling low in energy" is traduced by "lack of energy", in item 14 "losing sexual interest" is replaced by "losing interest in sex", in item 15 "feeling lonely" becomes "felling alone, in item 17 "feeling blue" becomes "feeling sad", in item 18 "ending one's life" becomes "ending your life", in item 21 "felling no interest" becomes "not interested in anything", in item 23 "worthless feeling" becomes "feeling useless", and in item 25 "sleep disturbance" was traduced by "problems sleeping".

Table 1 : Panel of General Practice experts

FPs Experts Number	Gender	English speaker	Years of practice activity	Academic researcher (years)	Publication	Teacher (Years)	Area of practice	LowerRate
	M: male F: female	Y: yes N: no			Y: yes N: no		1. < 2000 2. 2000-5000 3. > 5000	
1	M	Y	28	-	Y	N	3	1
2	F	Y	4	1,5	-	N	3	5
3	M	Y	20	20	Y	N	3	2
4	M	Y	25	2	Y	N	3	6
5	F	Y	20	5	Y	N	3	7
6	M	Y	8	5	Y	N	3	4
7	M	Y	32	30	Y	N	3	4
8	M	Y	30	20	Y	N	3	6
9	M	Y	3	20	Y	N	3	6
10	M	Y	14	3	Y	N	3	4
11	M	Y	25	-	Y	N	3	2
12	M	Y	20	-	Y	N	3	7
13	M	Y	23	13	Y	N	3	8
14	M	Y	26	23	Y	N	3	6
15	F	Y	23	15	Y	N	3	4
16	M	Y	26	10	Y	N	3	7
17	F	Y	24	4	Y	N	3	7
18	F	Y	20	10	Y	N	3	5
19	M	Y	32	-	Y	N	3	1
20	F	Y	19	5	Y	N	3	6
21	F	Y	25	10	Y	N	3	7
22	F	Y	18	10	Y	N	3	7
23	M	Y	5	4	Y	N	3	7
24	M	Y	25	20	Y	N	3	6
25	M	Y	25	20	Y	N	3	8
26	M	Y	20	15	Y	N	3	6
27	M	Y	5	5	Y	N	2	8
28	F	Y	6	4	Y	N	3	6
29	M	Y	25	20	Y	N	2	5
30	F	Y	20	10	Y	N	3	6
31	F	Y	10	10	Y	N	3	8

Table 2: Experts' rates on HSCL-25 items

: rates < 7 : average <7

FP EXPERTS	ITEMS HSCL 25 (Table 2.3)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	0	ranging 1 to 4 1	2	3	4
1		7	9	9	9	7	9	9	9	9	7	8	9	9	9	9	9	9	9	9	9	9	8	9	9	9	1	9	9	7	9	9	7
2		5	8	5	9	5	6	8	8	8	8	8	8	9	8	8	8	9	6	8	6	5	7	8	8	8	8	2	9	8	8	8	8
3		8	9	9	9	9	9	9	9	9	9	8	9	9	6	5	9	9	5	7	8	9	9	9	9	9	2	2	9	5	9	9	9
4		6	8	6	8	8	8	8	8	8	8	8	8	8	8	8	8	8	6	8	8	8	8	8	8	8	8	8	8	8	8	8	8
5		8	8	7	9	8	8	8	9	7	8	9	8	9	8	9	8	8	9	9	9	9	8	9	8	8	9	8	9	9	9	9	9
6		8	9	9	9	4	9	9	9	9	9	9	9	9	6	8	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
7		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	4	9	9	9	6	9	9	9	9	9	9	9	9	9	9	8
8		6	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9
9		8	9	9	9	9	6	8	9	9	7	9	9	9	9	9	9	9	9	7	8	8	7	9	9	9	8	7	9	9	9	9	8
10		5	9	8	9	9	9	9	9	9	9	9	5	8	8	8	5	8	9	8	8	8	7	9	5	4	5	8	9	7	8	9	8
11		8	8	3	3	8	9	9	9	9	9	9	3	9	3	9	9	9	9	8	9	9	8	8	3	3	2	9	9	9	8	8	8
12		9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	8	9	9	9	9	8	9	8	9	9	9	9	9	9	9
13		8	8	8	8	8	8	8	9	8	8	9	9	9	9	8	9	9	9	9	9	9	9	9	8	8	8	8	9	9	8	8	9
14		8	7	7	9	7	9	9	9	6	7	8	9	6	9	8	9	9	8	9	8	9	9	9	6	8	6	8	8	8	8	7	8
15		5	6	8	8	5	7	7	5	4	7	7	5	6	8	8	6	9	8	5	8	8	8	8	7	8	7	7	8	7	7	7	7
16		7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
17		9	8	7	7	7	8	8	7	9	7	8	8	9	9	9	8	9	9	8	9	8	7	9	7	9	7	8	9	7	9	9	9
18		6	6	9	9	9	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	9	6	6	6	5	5	5	5
19		9	7	4	9	7	5	7	8	6	9	6	5	9	3	7	9	9	9	3	9	9	9	9	9	9	9	1	9	5	5	5	5
20		9	6	9	9	6	9	9	9	6	9	9	6	9	8	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9
21		8	9	9	9	9	9	9	9	9	8	7	9	8	9	9	9	9	9	9	8	9	9	8	9	9	8	7	9	9	9	9	9
22		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9
23		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	7	9	9	9	9	9
24		8	8	8	8	6	8	8	8	9	8	6	8	9	6	8	9	9	8	6	9	9	6	9	9	9	8	8	9	8	8	8	8
25		9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
26		8	8	8	9	9	7	8	9	8	8	9	8	9	7	9	9	9	9	7	8	9	6	9	6	9	9	9	8	8	7	9	9
27		9	9	8	9	9	9	9	9	9	9	8	9	9	9	9	8	9	9	9	9	9	9	9	9	9	6	8	9	9	9	9	9
28		8	9	8	8	9	9	9	9	9	8	8	6	8	6	8	8	9	6	8	8	9	8	9	9	9	6	9	9	9	9	8	9
29		9	9	9	9	9	9	9	9	9	9	5	5	9	5	9	5	9	5	9	5	9	9	9	5	9	9	9	9	5	9	9	9
30		9	9	9	9	8	9	9	9	9	8	6	8	9	8	9	9	9	8	9	8	8	8	9	8	8	8	8	9	9	9	9	9
31		8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
Average 1-9		7,806	8,29	7,968	8,581	7,935	8,194	8,484	8,581	8,226	8,258	8,065	7,742	8,516	7,71	8,677	7,903	8,516	7,839	7,968	8,258	8,161	8	8,613	8,29	8,194	7,483	7,677	8,612	8,032	8,451	8,387	8,323

Table 3.1: HSCL-25: Original, Forward and Backward version

	ORIGINAL ENGLISH VERSION	FORWARD	BACKWARD
0	*Choose the best answer for how you felt over the past week:*	*Elija la respuesta que mejor describa cómo se ha sentido durante la semana pasada*	*Choose the best answer to describe how you felt over the last week*
1	Being scared for no reason	Se asusta sin motivo	Being scared for no reason
2	Feeling fearful	Siente miedo	Feeling afraid/fearful
3	Faintness	Debilidad	Weakness
4	Nervousness	Nerviosismo	Nervousness
5	Heart racing	Palpitaciones	Palpitations
6	Trembling	Tiembla	Trembling
7	Feeling tense	Se siente tenso	Feeling tense
8	Headache	Dolor de cabeza	Headache
9	Feeling panic	Siente pánico	Feeling panic
10	Feeling restless	Siente inquietud	Feeling restless
11	Feeling low in energy	Siente que le falta energía	Feeling a lack of energy
12	Blaming oneself	Se culpa a sí mismo	Blaming oneself
13	Crying easily	Llora con facilidad	Crying easily
14	Losing sexual interest	Pierde el interés sexual	Losing interest in sex
15	Feeling lonely	Se siente solo	Feeling alone
16	Feeling hopeless	Se siente sin esperanza	Feeling hopeless
17	Feeling blue	Se siente triste	Feeling sad
18	Thinking of ending one's life	Piensa en acabar con su vida	Thinking of ending your life
19	Feeling trapped	Se siente atrapado	Feeling trapped
20	Worrying too much	Se preocupa en exceso	Worrying too much
21	Feeling no interest	No siente interés por nada	Not interested in anything
22	Feeling that everything is an effort	Siente que todo le cuesta un esfuerzo	Feeling that everything is an effort
23	Worthless feeling	Se siente inútil	Feeling useless
24	Poor appetite	Falta de apetito	Poor appetite
25	Sleep disturbance	Problemas para dormir	Problems sleeping

ORIGINAL ENGLISH VERSION [26]	Items	1."Not at all"	2."A little"	3."Quite a bit"	4."Extremely"
	The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress. The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ³ 1,55. A cut-off value of ³ 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL 25 is 5 to 10 minutes.				
FORWARD		1. "En absoluto"	2-" Un poco"	3-" Bastante"	4- "Mucho"
	La puntuación del HSCL-25 se calcula dividiendo la puntuación total (sumando la puntuación de todos las preguntas) entre el número de respuestas (varía entre 1,00 y 4,00). Se usa habitualmente para medir el malestar psicológico. El paciente se considera un "probable caso psiquiátrico" si el valor medio del HSCL-25 es >= 1,55. Por lo general se usa un valor de corte de >= 1,75 para el diagnóstico de depresión mayor, definida como "un caso que necesita tratamiento". Este valor de corte se considera un predictor válido de un trastorno mental, evaluado de forma independiente mediante entrevista clínica, aunque depende en parte del diagnóstico y el género. El tiempo de administración del HSCL-25 es de 5 a 10 minutos.				
BACKWARD	Items	1."Not a bit"	2."A little bit"	3."Quite a bit"	4- A lot
	The HSCL-25 score is calculated dividing the total score (the sum of the scores of all the questions) by the number of items answered (from 1 to 4). It is usually used to measure the level of anxiety. The patient is considered a "probable psychiatric case" if the average of the HSCL-25 score is >=1,55. A cut-off point >=1,75 is generally used for the diagnosis of major depression, defined as " a case that needs treatment". This cut-off is considered a valid predictor of mental disorder, assessed in an independent way by a clinical interview, although it depends, in part, on the diagnosis and gender. The administration time of HSCL-25 is from 5 to 10 minutes.				

ORIGINAL ENGLISH VERSION [27]	The HSCL-25 score is based on pencil-and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1 to 4.
FORWARD	La puntuación HSCL-25 se basa en un cuestionario autocumplimentado con lápiz y papel, de 25 preguntas sobre la presencia y la intensidad de ansiedad y síntomas depresivos en la última semana. Los participantes responden una de cuatro categorías para cada ítem, en una escala de cuatro puntos que van desde 1 a 4.
BACKWARD	The HSCL-25 score is based on a survey that is self-administered with pen and paper. It has 25 questions about the presence and intensity of anxiety and depressive symptoms over the last week. The participants answer one of the four categories for each item on a four-point scale ranging from 1 to 4.

Table 3.2: HSCL-25: original version/ Forward version/ Backward version

Discussion

Strengths

The strength of the study is based on its methodology: the Delphi process adapted for Forward-Backward translation. The Delphi process can be conducted quickly so there is no lost of sight, does not required any face-to-face meeting, preserve anonymity, limits conflicts of interest and liberates from geographical constraints. It is a rational and no statistical representativeness, so the size of the expert's sample is correct.(45)

The Likert scale is an international validated, qualitative and ordinal scale. The ranking 7 or above guaranteed an adherence to the translation.(43)

Forward/Backward translation is an international validated process of translation and adaptation of instruments. The Forward translation process respects the faithfulness of meaning in English and Castilian and integrates idiomatic expressions, colloquial health phrase and emotional terms in common use.(44)

The HSCL-25 seems to be a very stable questionnaire because a large proportion of items obtained a rate of 7 or above. The Forward-Backward translation was achieved according with protocol and a consensus on Castilian translation of of the HSCL-25 was reached in one round.

The ranking 7 or above guaranteed an adherence to the translation.

Limits

Information bias:

The NI strictly followed the Delphi round method protocol: he sent the same content to all experts sentence by sentence so information bias was controlled. The proposed translation and the rules of procedure were clearly written. All GP-experts rated all items and they wrote comments when rating less than 7. The short delay of response avoided information bias.(46)

Selection bias:

Translators were chosen with care, and they met the selection criteria (they were knowledgeable about health care terminology).

GP Experts were sufficient (31GPs) according Delphi procedure. Their selection criteria were respected: all experts were English speakers, General Practitioners and Academic Researchers.

None had teaching activity but 96.8% (30/31) had publication. They were native from Castilian and Castilian was their native language. Years of practice distribution is good and representative of Castilian GPs' population, but the most represented are GPs with from 20 to 30 years of practice (41.94%).There was no lost sight because there was only one round.

To constitute the panel, experts were chosen to ensure a maximum of heterogeneity, to increase its representativeness.(36)

Most of them worked in a city > 5000 (29/31=93.5%). This criteria is not heterogeneous and there could be a recruitment bias, but it can be explained with high proportion of academic researchers, and Spanish Primary Care organization promoting Health Centres (from 4 to 10 GPs' association usually).

Males were more represented (64.5%).

Confusion bias:

Delphi process is an international validated tool. It preserves anonymity, limits domination effect and conflicts of interest effects.

Forward-Backward is an international consensual process of translation. Particular attention was paid to the translators' selection. There was an official translator in Forward, and a philologist in Backward. They respectively took part in two different translation teams, with GPs. They had knowledge about health care terminology and had Castilian for native language. Backward translation did not involve the same translators as the Forward's; it was undertaken blind. (47)

Participants' anonymity was respected during the whole process (NI sent the proposed translations in « single recipient » mails and identification numbers were used for responses analysis.

No linguistic and meaning differences should be founded between the original version and the final version but differences and commentaries were relieved.

Anxiety items seemed to be easier to translate than depressive items. It collected few comments and there were few changes in Back translation (two changes). Depressive items had many variations (eight changes), maybe because depressive symptoms are more subjective. The method of use in practice of HSCl-25 was also much discussed in the forward translation and differences were also relieved.

A possible confusion bias could exist, related to the cultural impact. Those aspects will be analysed with a cultural check.(48)

Conclusion

FPDM study aims to find a diagnostic tool for depression, which can be used all around Europe. The first and the second steps selected HSCL-25 as the best tool to diagnose depression in General Practice setting.

General Practitioners need to get it in their practice languages for both investigation and clinical use. The third step consisted in translating this tool in the language of each country taking part in FPDM study, with the support of European General Practice Research Network (EGPRN). Reliability of each translation is an essential element to make this tool widely usable both in Spain's linguistic areas and on a European scale. This will allow reliable comparisons of the diagnosis assessment of depression and treatment practices. The GPs will exchange more objectively with healthcare authorities and psychiatrists on the prevalence, incidence and treatment of depression in primary care.

To meet such objectives, all translations followed the same well-tried formal consensus method. We performed a consensual translation of HSCL-25 in Castilian using a Delphi procedure adapted for a Forward-Backward translation. This procedure aimed to produce the best translation, taking into account cultural differences and Castilian special features.

The translation process involved experienced translators and a highly proficient panel of experts. The consensus was reached in one Delphi round. Back-translation will be used to perform a cultural check. It will confirm if each translated excerpt keeps the same meaning as the original and ensures the homogeneity of the various translations.

During the next step (fourth phase), every national team will test HSCL-25 to ensure its ergonomics in a general practice setting.

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ANNEXES

Annex 1: HSCL-25 Hopkins Symptom Checklist

Département Universitaire de Médecine Générale
22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3
Tél : 02 98 01 65 52 – fax : 02 98 01 64 74

Choose the best answer for how you felt over the past week:

Items		1: "Not at all"	2:"A little"	3:Quite a bit":	4: "Extremely"
1	Being scared for no reason				
2	Feeling fearful				
3	Faintness				
4	Nervousness				
5	Heart racing				
6	Trembling				
7	Feeling tense				
8	Headache				
9	Feeling panic				
10	Feeling restless				
11	Feeling low in energy				
12	Blaming oneself				
13	Crying easily				
14	Losing sexual interest				
15	Feeling lonely				
16	Feeling hopeless				
17	Feeling blue				
18	Thinking of ending one's life				
19	Feeling trapped				
20	Worrying too much				
21	Feeling no interest				
22	Feeling that everything is an effort				
23	Worthless feeling				
24	Poor appetite				
25	Sleep disturbance				

The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress.

The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ³ 1,55.

A cut-off value of ³ 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender.

The administration time of HSCL 25 is 5 to10 minutes.

Annex 2: informed consent (to translate in your language)

Département Universitaire de Médecine Générale

22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3

Tél : 02 98 01 65 52 – fax : 02 98 01 64 74

INFORMATION NOTICE

International Investigator Senior Coordinator

Name: Nabbe Patrice

Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3

International Developer

Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3

National investigator senior coordinator:

Name:
Address:
National developer:

Dear Madam or Sir

You are invited to participate in a survey by C. FLAMANT(trainee in general practice, GP…). The department of general practice from BREST. is the national developer of that survey. She is responsible for it and assumes its organization.

Mrs/Mr …….. will explain his/her work to you. If you decide to participate you will be asked to sign a consent form. This signature will confirm that you did agree to participate.

1. Course of study

A Delphi procedure. This Delphi procedure will be fully anonymized and it will be impossible for a study reader to identify you.

2. Potential risk of study

There are no risks associated with your participation in this study

3. Potential benefits of the study

There is no potential benefit to this study

4. Voluntary participation

Your participation to this study is entirely voluntary.

You are free to refuse to participate and to terminate your participation in the study at any time and without incurring any liability or any injury of this fact and without causing consequences.

In this case you must inform the investigator of your decision

In the event that you withdraw your consent, we will conduct a computer processing of your personal data unless written objection on your part.

During the study, your investigator will notify you, if new facts might affect your willingness to participate in the study.

5. Obtaining complementary informations

If desired, Patrice Nabbe or local national investigator (phone number), who can be reached at telephone number: 00 33 674 36 43 22 at any time can answer all your questions about the study.

At the end of the study, and at your request, your investigator will inform you of the overall results of this research.

6. Confidentiality and use of medical or personal data

As part of biomedical research in which the DUMG Brest, Patrice Nabbe and your national investigator offer to participate, a treatment of your personal data will be used to analyse the results of research in light of the objective of that study which was presented to you.

To this end, the data collected, including any survey and the data on your lifestyle will be forwarded to the promoter of the research where the data will be processed in this study.

Those data will be anonymized and their identification will be held with a code number.

Staff involved in the study is subject to professional secrecy.

These data may also, under conditions ensuring their confidentiality be transmitted to the national or European health authorities.

Under the provisions of Law you have the right to access and modify. You also have the right to object to the transmission of data covered by professional secrecy.

If you agree to participate in this study, thank you to complete and sign the consent form. You will keep a copy of it.

Annex 3: Consent Form for each leader

Consent Form (for each leader with department of general practice, Brest, France

Promoter : Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex

Dr: NABBE Patrice

Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3, FRANCE

National leader investigator name

Address: ……..

University:

Asked me to participate in a Forward-Backward translation.

I had time to reflect on my involvement in this study. I am aware that my participation is completely voluntary and that the study will entail no additional cost to my charge.

I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences.

I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter.

I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me.

My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law.

Done in two originals

at……, the

dd/mm/yyyy

Name, first name of national leader: Name, first name of the interviewee:

Signature:

Annex 4: Consent Form for each national team

Consent Form (for each national leader with each member of local national team)

Promoter : Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3

Dr:……
……

Address:
……..

Local investigator name

Address:
……..

University:

Asked me to participate in a Delphi consensus.

I had time to reflect on my involvement in this study. I am aware that my participation is completely voluntary and that the study will entail no additional cost to my charge.

I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences.

I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter.

I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me.

My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law.

Done in two originals

at……, the

dd/mm/yyyy

Name, first name of investigator: Name, first name of the interviewee:

Signature:

FLAMANT Caroline – What is the translation of HSCL-25 in Castilian; A consensus procedure by delphi-round and Forward-Backward translation. 38 pages, tables, annexes.
Thèse Medecine : Brest 09/14

RESUME
Introduction : Les médecins généralistes européens sont le premier recours des patients dépressifs. Les patients de plus de 50 ans multi-morbides sont plus à risque d'épisodes dépressifs. Les variations interindividuelles et interculturelles peuvent modifier l'expression des symptômes. En soins primaires, peu d'outils diagnostiques sont adaptés et utilisés.
L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) a pour objectif de sélectionner un outil diagnostique de la dépression en médecine générale. Des recherches européennes collaboratives entre médecins généralistes de différents pays et entre médecins généralistes et psychiatres pourront être réalisées.
Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25-items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie, versus DSM.
Objectif : L'objectif était de traduire la HSCL-25 en Castillan sans perte de sens mais cette traduction devait être compréhensible par les médecins et les patients, en prenant en compte les particularités culturelles et linguistiques du Castillan.
Méthode : Une procédure Delphi adaptée avec traduction Aller-Retour a été utilisée. Une traduction de l'Anglais au Castillan a été soumise par procédure Delphi à un panel d'experts en soins primaires. La traduction retour a été réalisée en aveugle de l'original.
Résultats : Le panel d'experts répondait aux critères d'inclusion. La traduction castillane a été validée après deux tours. La traduction retour en anglais a été produite.
Discussion : Le choix d'une méthode de traduction Aller-Retour par procédure Delphi adaptée et la qualité du panel d'experts garantissent une traduction castillane validée et fiable de la HSCL-25. La prochaine étape est une analyse culturelle de la traduction qui assurera la reproductibilité sémantique entre la version originale et la traduction.

ABSTRACT
Introduction: General Practitioners (GPs) are the first port of call for depressive patients in developed countries. The multi-morbid patients over 50 years are more at risk. Inter-individual and intercultural variations may change the symptoms expression. Few diagnostic tools are adapted and used by GPs.
Family Practice Depression and Multimorbidity (FPDM) study by European General Practice Research Network (EGPRN) aims to select a depression diagnostic tool in primary care to undertake collaborative research involving GP's and Psychiatrists throughout Europe.
The two previous steps of FPDM found that the Hopkins Symptom Checklist in 25-items (HSCL-25) was the most appropriate tool according to effectiveness, reproducibility and ergonomics criteria versus DSM.
Objective: This study aimed to translate HSCL-25 in Castilian, keeping its meaning. This translation must be understandable by practitioners and patients, according to Castilian cultural and linguistic features.
***Method*:** A Delphi method adapted for a Forward-Backward translation was used. The Forward translation from English to Castilian was submitted by Delphi procedure to a panel of primary care experts. The Backward translation was performed blind.
Results: The inclusion criteria of panel were followed. The Castilian translation was accepted in one round. English back-translation was produced.
Discussion: Delphi method adapted for a Forward-Backward translation and the experts panel quality ensured a validated and reliable Castilian translation of the HSCL-25. The following step will consist in a cross-cultural check. Concordance between the original HSCL-25 and the Back-translation will be analysed.

MOTS CLES :
Depression
Translation
HSCL-25
Delphi
Castilian

JURY :

Président : Pr. JY LE RESTE

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